



DEPARTMENT OF HEALTH & HUMAN SERVICES

m37607

New York District

**Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202**

WARNING LETTER NYK 2000-72

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

May 16, 2000

Mr. Lawrence A. Gaus, Owner
L.A.G. Sales Company
454 Perrysville Avenue
West View, Pennsylvania 15229

Dear Mr. Gaus:

The Food and Drug Administration (FDA) has information which shows your firm violated the Federal Food, Drug, and Cosmetic Act.

On April 27, 2000, your firm imported canned coffee into the United States under Entry No. 702-2961708-2. An investigation conducted by this office revealed the entry was not held intact, and has been distributed.

We have requested U.S. Customs to order redelivery of the entry.

This action taken by your firm is in violation of 21 CFR 1.90, which requires an importer to hold an entry intact pending receipt of a "May Proceed" or "Release Notice" from the FDA. A "Release" by the U.S. Customs Service is a conditional release, which merely permits you to take possession of the shipment. When other Federal Agencies, such as the FDA, also exercise jurisdiction over a product offered for importation, their release must be obtained before a product may be legally distributed.

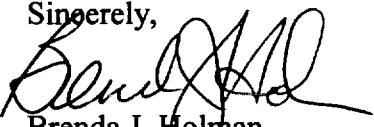
Failure to promptly correct these violations and prevent future violations may result in regulatory action without future notice, such as seizure or automatic detention, to ensure that imported products are held intact until released by FDA. It is your responsibility, as the owner/importer, to ensure imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

Within fifteen (15) working days of the receipt of this letter, please notify our office in writing of the specific steps you have taken to correct the violation(s), including an explanation of each step being taken to prevent a recurrence of the violation(s). Your response should be directed to Mark P. Prusak, Supervisory Investigator.

A copy of this letter, except for any confidential, personal, or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will be on public display with any confidential, personal, or commercial information purged.

If you require further information, you may contact Mark P. Prusak at (716) 551-4461, Extension 3153.

Sincerely,



Brenda J. Holman
District Director

cc:

John Van Wallaghen, Northern Border Operations Manager
U.P.S./Trans Border Customs Services
P.O. Box 800
Champlain, New York 12919